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ABSTRACT

The goal of this study was to produce an improved medical consent form. This form was designed to record the informed consent discussion between doctor and patient which should include an explanation of what procedure will be performed, by whom, why, the risks, and the alternatives. Patients, doctors, and hospitals may all benefit from the use of consent forms. Three considerations in devising a consent to surgery form included the best way to improve readability for patients, specificity of information, and improvement of design to make it more frequently utilized. The revised form was evaluated by lawyers, nurses, doctors, and subjects from the general public. The author believes ideal documents cannot be produced until all patients are willing to be fully informed and all doctors are willing to inform them. (DWH)

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Informed Consent: Reality or Illusion?

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and John R. Hayes

Carnegie-Mellon University

June 1981

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Informed Consent: Reality or Illusion?[1]

Carol J. Janik, Joyce Hannah Swaney, Sandra J. Bond,
and John R. Hayes

Carnegie-Mellon University

Introduction

Health care in the United States is changing significantly in a number of areas. New drugs, procedures, and devices to treat illness are being developed through the joint efforts of practitioners and researchers. A new class of para-professionals--including nurse practitioners and a variety of specialized technicians--is emerging to put the new technology into practice.

One area in which change is particularly noticeable is the doctor/patient relationship. Important questions are being raised about who should bear the burden of making decisions about treatment. Do patients have a real choice in deciding their treatment, or is their decision to undergo a procedure merely an echo of their doctor's recommendation? How much information should patients be given about their condition and the proposed treatment? What is the best way to communicate that information?

As document designers, our interest in these questions focused on consent forms such as that shown in Figure 1. Examinations of the forms being used by major hospitals in Pittsburgh suggested that there was considerable room for improvement. The major goal of our study was to produce a better consent form.

I. Pre-Design: The Function of Consent Forms

To approach the design task intelligently, we first had to learn the purposes consent forms are intended to accomplish. We began our study with a survey of the literature, by consulting with a group of lawyers who specialize in hospital law, and by meeting with a patients' rights group. This research helped us answer important questions about consent forms, such as: Why are they needed? Who needs them? How are they used?

The purpose of consent forms is closely tied to the doctrine of informed consent.

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[1] To appear in *Information design journal*.

The Doctrine of Informed Consent

The idea of consent as a legal concept began to emerge around the beginning of this century. This early concept was concerned only with whether or not a patient consented to treatment, and was based on the premise that "a patient has the right to determine what shall be done with his own body" (Annas 1975). More recently the consumers' rights movement, and the medical malpractice crisis which occurred around 1975–76, along with a growing body of case law, helped to develop and refine the concept. Thus, in addition to getting a patient's consent, the courts determined that it is necessary for doctors to give patients information about treatment so that patients can make an intelligent decision and give informed consent (Horty 1980).

Although the legal requirements of informed consent differ from state to state, it is generally accepted that the informed consent discussion between doctor and patient should cover five items of information: what is to be done, why, by whom, the risks associated with the procedure, and the alternative methods of treatment that are available (Horty 1981). This guideline is an important step because it specifies what information should be given. However, it does not deal with the question of how much. In fact, the current area of major concern is with the degree of disclosure, that is, how much information, particularly about risks, should doctors give their patients? Will this information be harmful or helpful? Do patients really want this information? There is a growing body of literature in medical and legal journals dealing with these questions.

The most dramatic case against full disclosure is that there may be hazardous consequences of telling a patient of the possible risks of surgery. For example, Patten and Stump (1978) described two cases in which the patients refused to undergo major surgery because of the risks involved, and the patients later died. However, relating death directly to the disclosure of risks is rather simplistic. The important question concerns the patient's right to make the choice. Although this question cannot be ignored, there is no simple answer. The bulk of the literature we surveyed was very positive about the benefits of informing patients (Hassard 1973; Annas 1975; Goldsmith 1975), and tends to support the view that "doctors should accept education of the patient through the process of informed consent as a worthwhile therapeutic goal" (Rennie 1980).

A number of studies have been done which examine the notion that discussing risks will

unnecessarily alarm patients. One study which surveyed patient reaction to this type of information suggests that while full disclosure is desired by some patients, it is not for everyone (Rosenberg 1973). In that study, 100 patients were given detailed information about the possible complications of a diagnostic procedure. Seventy-three percent of the patients said that this information would have helped them to make an intelligent decision about whether they would have undergone the procedure. However, 50% of the patients surveyed said that they would have withheld consent because of one complication or another.

Another study surveyed patients who were to undergo angiography, also a diagnostic procedure (Alfidi 1971). The hypothesis was that the patients would refuse the procedure after being informed of its possible complications. Although many of the patients said that the information was disturbing, the majority of them said that they appreciated receiving it, and 228 out of 232 patients consented to the procedure. This study comes closer to revealing the real needs of patients because the patients surveyed were actually going to undergo the procedure. In the previous study, the patients were given a hypothetical situation unrelated to their condition and were then asked to predict what they would do.

A third study measured emotional response in patients to carefully prepared, written information about the benefits and risks of hysterectomy (Denney et al. 1975). Of the 40 subjects in the experimental group who were given the specially prepared booklet, 37 reacted favorably to the booklet; 11 felt it perhaps contained too much information; none withheld consent to surgery. In addition, patients who read the booklet did not show higher preoperative anxiety levels than those who had not read it, and more importantly, postoperative anxiety levels were significantly lower for patients who had read the booklet.

What is the purpose of a consent form?

The main purpose of a consent form is to record the informed consent discussion between the doctor and the patient. As we mentioned earlier, informed consent is consent given when the doctor explains to the patient five items of information (what, by whom, why, the risks, the alternatives). This exchange of information about treatment between the doctor and the patient is the heart of informed consent.

It is important to distinguish between informed consent and the consent form. A patient may feel compelled to sign a consent form even when the doctor has not explained the treatment. In such cases, of course, there is no informed consent. "By failing to distinguish between informed consent and its documentation, the legal profession has precipitated the most

egregious misconception by physicians concerning informed consent--namely, that if a consent form is signed, informed consent is given" (Vaccarino 1978).

Who benefits from consent forms?

There are three groups who may benefit from the use of consent forms: patients, doctors, and the hospitals in which treatment is given. Patients benefit because consent forms help them to exercise their right to give informed consent. Consent forms remind doctors that patients have a right to information about treatment and about the alternative choices available to them. Doctors benefit because consent forms may help to resolve misunderstandings in malpractice suits. When a medical procedure has an unfavorable outcome, patients or their relatives may not remember that the patient was informed of this possibility. The consent form can serve as a record to protect the doctor (Goldie 1972). Hospitals benefit because consent forms can serve to separate hospitals from malpractice disputes between doctors and patients. Indeed hospitals, on the advice of the lawyers who represent them, are very active in promoting the use of consent forms.

II. Our Revision

From the previous discussion it is clear that revising a consent to surgery form presents problems beyond merely simplifying the language and improving the visual design of the form. In particular, we identified three major areas of concern:

1. What is the best way to meet the needs of the people who use the form? More specifically, what is the best way to characterize patients, who are a subset of the general public and who have widely different reading abilities and information needs?
2. How explicit should the information in a consent form be?
3. Is there a way to design consent form so that it will be used as it should be and thereby improve the informed consent process?

Figure 1 shows a consent to surgery form that is typical of those being used by major hospitals in Pittsburgh. Figure 2 shows our revision.

What is the best way to meet the needs of the people who use consent forms?

A number of studies show that consent forms are not readable (Grundner 1978, 1980;

Figure 1: Original Consent Form

PATIENT: _____

DATE: _____ TIME: _____ A.M. P.M.

CONSENT TO OPERATION OR OTHER MEDICAL PROCEDURE

I hereby acknowledge and understand that the nature of the procedures authorized by this form, the possible alternative methods of treatment, and risks involved or the probabilities of success or failure have been fully explained and disclosed to to me personally by Dr. _____.

1. I hereby authorize the performance upon _____ of the following procedure
(Myself or Name of Patient)

_____
(Name or Description of Operation or Other Procedure to be Performed in the Language of Laymen)

2. I hereby authorize Dr. _____ and/or such assistants, including resident physicians, as may be advisable or necessary, to remedy the condition or conditions which are indicated by the diagnostic studies already performed.

3. I have also been informed that there are other risks such as severe loss of blood, infection, cardiac arrest, etc. that are attendant to the performance of any surgical procedure. I acknowledge that no guarantees have been made to me concerning the results of the operation or procedure.

4. I, Dr. _____, affirm that I have personally communicated to the patient the information referred to above, have offered explanations to the best of my ability, have answered the questions raised by the patient and have explained the contents of this consent form to the patient who has signed it in my presence.

_____ _____
(Date) (Signature of Physician)

5. I, _____, (Patient or Person Authorized to Consent for the Patient) attest to the fact that I have been given the opportunity for questions and answers regarding the condition(s) and procedure(s) outlined in this consent form and the contents thereof have been fully explained to me. The blanks appearing on this form have been completed or deleted prior to my signature.

_____
(Signature of Patient or Person Authorized to Consent for Patient)

Witness

_____

Patient Signature to be

Figure 2: Our Revision

Patient's Name _____

City Hospital
Consent to Surgery

Part 1
Planned Treatment
To be completed by the doctor, in common terms, before the patient signs this form.

1. Dr. _____ has explained to me that:
   a. I have the following condition: _____
   _____
   _____
   b. my condition needs to be treated because: _____
   _____
   _____
2. I authorize Dr. _____
   to operate on me or to appoint someone else to operate on me.
   The operation to be performed on me is as follows: _____
   _____
   _____
   _____
3. The doctor has explained that:
   a. the following risks are involved in the operation: _____
   _____
   _____
   _____
   _____
   b. all surgery involves risks such as severe loss of blood, infection, and heart stoppage;
   c. the surgery will be done in a responsible manner by licensed personnel. No guarantee has been made that the surgery will improve my condition;
   d. my condition could be treated in the following other ways which are not being used on me at this time: _____
   _____
   _____

Part 2
Additional Surgery
To be completed by the patient.

My doctor has explained to me that sometimes during surgery it is discovered that additional or other surgery is needed. If I need additional or other surgery during my operation,

☐ I authorize the doctor to proceed.

☐ I do not authorize the doctor to proceed.

Patient's Name _____

Part 3
Disposition of Tissues
To be completed by the patient.

I request that anything removed from me:

☐ be disposed of by the hospital as usual, or

☐ other: _____

Part 4
Signatures
To be completed only after Parts 1, 2, and 3 are filled in.

- I declare that I have personally explained the nature of the patient's condition, the need for treatment, the operation to be performed, and the risks and alternatives listed in Parts 1, 2, and 3:

☐ to the patient.

☐ to the patient's closest relative or guardian:

Name _____

Address _____

Phone _____

I have given the patient or the person named above an opportunity to ask questions which I have answered as fully as possible.

Signature of Doctor _____

Signature of Witness _____

Date _____ Time _____ am pm

- The doctor has explained all of the information in Parts 1, 2, and 3, to me and has answered my questions.
I understand that a copy of this completed form will be given to me after I sign it.

Signature of Patient _____

Signature of Witness _____

Date _____ Time _____ am pm

- The patient is unable to consent for the following reason: _____

I therefore give consent on the patient's behalf.

Signature of Closest Relative or Legal Guardian _____

Relationship to Patient _____

Signature of Witness _____

Date _____ Time _____ am pm

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Morrow 1980). To improve readability, therefore, we dropped unnecessary words like "hereby" and "thereof," and simplified other words we thought might give people trouble, like "cardiac arrest." We also simplified repetitious phrases like "acknowledge and understand" and "explained and disclosed."

The first content change we made was to narrow the scope of the form to include surgery only. This further helped to simplify the language since it was no longer necessary to repeat phrases like "surgery and/or procedure." We recommend that a separate form (or forms) be used for non-surgical procedures.

We then reorganized the form into four main parts and added instructions about who was to complete each part. *Part 1* lists the five items of information required for informed consent. Notice that we kept the rather negative statement about "no guarantees" but tried to balance it by adding a positive statement directly in front of it. *Parts 2* and *3* are not required for informed consent, but in practice these decisions frequently need to be made before undergoing surgery. We felt it was particularly important for patients to be able to choose whether or not they wanted to authorize additional surgery. *Part 4* provides space for the signatures of those involved: the doctor, the patient, the relative or legal guardian if the patient is unable to consent, and the witnesses.

We next consulted with a graphic designer to improve the visual design of the form. She used white space, headings, and boldface type to reinforce the logic of our organization and to help guide the users through the form. Although we could have reduced the size of our form to one page by using smaller type, we chose to use 9 pt. type, which is easier to read (Wright and Barnard 1975), especially for older patients.

How explicit should the information in a consent form be?

The information in the consent form shown in Figure 1 is not explicit. For example, the statement at the top of the form says, in part, that the patient understands the nature of the procedure, the alternative methods of treatment, and the risks involved. But what exactly is the nature of the procedure? What are the alternatives? And what are the risks? The form does not give this information, and it would be impossible for anyone reading the form to infer that information. Another example is Statement #4, which says in part that the doctor has communicated to the patient the information referred to above. Again, where is that information? Statement #1 provides a blank space for the name or description of the

operation or procedure. It is the only place on the form where information about treatment is specific. The other 12 blanks on the form are for names and signatures, or for date and time.

It is clear that this type of form is not an accurate record of informed consent because it does not give specific information about what has been discussed. It is easy to see how a patient could sign such a form without being informed. In addition, statements in this form are too general to protect either the hospital or the patient in case of an informed consent suit. It would be the patient's word against the doctor's as to what information had been discussed. Nor would this type of form be very effective in helping the patient to remember important information about treatment.

In *Part 1* (Figure 2) we revised the statements about treatment, risks, and alternatives to include blank spaces so that doctors can write in specific information for individual patients.

For those patients who want to be informed, our revision is a welcome improvement. It ensures that they have been given the information necessary to make an intelligent decision about their treatment. But what about those patients who don't want to know detailed information about their condition and the proposed treatment? Our decision to make this type of information explicit reflects our personal bias in favor of full disclosure. It also reflects the literature on this issue, which suggests that although full disclosure is not for everyone, it has legal and therapeutic advantages.

Our revision may present a different problem for doctors. Medicine is not an exact science, and doctors are not fortune-tellers. Many doctors fear that if they fail to list a possible complication, or a previously unknown complication, and if the complication occurs, they may be faced with a suit. Fortunately, the case law on informed consent has recently developed a rule of thumb to help doctors decide how much information they are legally required to give concerning risks. This rule says that a doctor must inform the patient of all serious risks, even if rare, and all minor risks that have a high probability of occurring. In addition, doctors are not liable for failing to disclose a risk they were not aware of and did not have to be aware of (Horty 1980). This problem with disclosure can also be avoided if doctors establish a healthy relationship with their patients. Even if there are unsatisfactory results from surgery, a patient is not likely to take legal action if good communication and rapport are established between the doctor and patient (Goldsmith 1975).

Can a well-designed consent form improve the informed consent process?

We realize the limitations of using a form to change behavior. For example, even a clearly written, well-designed consent form is not likely to affect either the medical treatment a patient receives or the process by which the patient is informed if the form is not read by the patient, or if it is used by an insensitive or incompetent doctor.

Ideally a consent form should be signed at the time informed consent is given. Only in this way can the form be an accurate record of informed consent. But in practice the forms are not used this way. What often happens is that the consent form is not signed until much later, usually the evening before the operation. As a result, there is often a lapse of days, or even weeks, between the time the patient talks to the doctor and the time the form is signed. During that period, patients may forget important information or questions they may have had about the treatment. Thus, their signature may no longer reflect informed consent.

A number of studies have focused on patient recall of the information necessary for informed consent. In general, recall is poor (Robinson and Merav 1976; Priluck et al. 1979; Cassileth et al. 1980; Leeb et al. 1976). These studies suggest that a well-designed, informative consent form could be used as an aid to patient recall.

Using a consent form to inform will only be effective if the patient reads it. We were surprised to learn that many patients do not read consent forms, for a number of reasons: they won't read it because they do not want to be informed; they can't read it because they are in some form of acute distress (such as labor); or they don't read it because the way in which it is presented does not encourage them to.

Two changes we made in the form were designed to encourage doctors to use consent forms as they should be used and thereby ensure that patients are giving informed consent to treatment.

First, by devoting one section to signatures, we hoped to emphasize 1) the importance of reading the form, and 2) that the process of giving and getting informed consent depends on the joint efforts of the doctor and the patient. In particular, by including space for date and time next to each signature, we hoped to encourage doctors to get the form signed at the time informed consent is given. Any time span between when the doctor fills out the form and signs it and when the patient reads it, fills it out, and signs it will be apparent in our revision.

Second, the use of blank spaces in *Part 1* makes the document more informative and allows the doctor to tailor the information to the specific needs and situation of the patient. We recommend that doctors use our form as a guide for the informed consent discussion with their patients, filling in the blanks as the discussion proceeds, then getting signatures at the time consent is given.

In addition, giving a copy of the signed consent form to patients will serve as a guide and a reminder to them about the details of their condition and proposed treatment.

III. Post-Design: How Does Our Revision Compare With the Original?

We used a number of techniques to evaluate our revision.

1. We showed our revision to the group of lawyers we had consulted at the beginning of our study. Aside from a few word changes, they were very pleased with our revision and assured us it was legally sound.

2. We compared readability scores of 10 consent to surgery forms being used by major hospitals in Pittsburgh with our revision. Table 1 shows that, in terms of readability, our revision was a definite improvement. Although we realize the limitations of such scores (particularly for forms, where there is a minimum of text), the courts still rely on them to help make decisions in informed consent cases. Like the gas mileage estimates given for new cars, the value of readability scores lies in the comparisons we can make.

3. We further evaluated our revision by testing user comprehension on 24 people from the general public. We gave each subject a page which contained a brief case study describing a person who needed an appendectomy. In addition, we gave half of the subjects the original consent form which had been filled out by a doctor based on the information in the case study. We gave the other twelve subjects our revised consent to surgery form which had also been filled out by the same doctor. Subjects were then asked to answer six questions using the information from the materials they were given. We measured the time it took each subject

Table 1

Comparison of Readability Scores* on Consent to Surgery Forms in Use and Our Revision

	Recalculated Flesch Score	Fog Index
Form 1	14.2	19.2
2	16.4	20.3
3	16.7	22.7
4	16.2	20.4
5	16.5	20.4
6	16.2	20.9
7	18.5	21.9
8	16.0	21.2
9	16.2	21.2
10	13.2	17.9
Average	16.0	20.6
Our Revision	9.2	12.3

*Both the Recalculated Flesch Score and the Fog Index correspond to school-grade reading level. The acceptable reading level for most Americans is twelfth-grade or below.

to answer the questions and the number of errors each subject made.

There was no significant difference in the length of time needed to answer the questions. However, the subjects who had the "original" version made a combined total of 14 errors, while the subjects who had our revision made a combined total of 8 errors.

We also asked the subjects if they would read a consent form before signing it. All subjects said that they would definitely read it; some were very emphatic about this. These responses are in direct contrast to what often really happens with consent forms, i.e., many patients do not read them.

4. We showed our revised consent to surgery form to six nurses and asked them to comment on it from their point of view. In general, their reactions were positive. In particular, all of the nurses approved of our revision beacuse it requires the doctor's signature (four of the consent to surgery forms we collected from major Pittsburgh hospitals do not have a space for the doctor's signature), and because it includes blank spaces to list risks and alternatives. Two of the nurses felt it would be impossible to get doctors to use our form because of the time required to fill it out. In addition, two nurses commented on the length of our form: one felt that the length would overwhelm patients; the other said that patients might feel relieved to know that they were getting a fuller explanation of their condition and the proposed treatment.

5. We also showed our revision to five medical doctors. As a group, they reacted negatively to the use of consent forms and tended to focus their remarks on the care they take to inform their patients. Three of the doctors stated or implied that the fewer blanks on a consent form, the better. These three doctors were surgeons.

The specific comments of three of the doctors were especially interesting. One doctor suggested that patients should fill in the information in *Part 1* as a test of their understanding and to insure that they pay attention to the form. However, she admitted that this would be a problem for most patients because she feels that most patients don't want to know enough about their condition and treatment to be able to fill it out accurately.

The second doctor liked the language in our revision and thought statement #3.b. in *Part 1* was a good idea. However, he questioned the statement about alternatives and asked why we had included it. As a surgeon, he felt that when he recommends surgery, there are no alternatives. However, this doctor reacted favorably to our suggestion to use our consent form as a guide to his discussion with the patient, and to get the form signed at the time the

patient consents to treatment.

The third doctor gave particularly detailed and helpful comments. His strongest objections were to the statements about "no guarantees" and "alternatives." He suggested a way to expand the statement about no guarantees to make it more reasonable and less threatening: "I am aware that the practice of medicine is not an exact science and I acknowledge that certain circumstances may modify the end result of the operation. *Because of this* [his emphasis] no guarantees can be given about everything that is written above." Like the second doctor, he also felt that there is often no alternative to surgery, except not to have the operation, which he would not recommend. He agreed that it might be helpful to add another clause to this statement to give the doctor space to state why the alternatives listed are not being recommended.

Conclusion

Our study of consent forms illustrates that revising a document involves more than just changing words and breaking up long sentences. Issues related to the purpose, use, and users of a document present problems in making decisions not only about what information should be included, but also about how that information should be presented. Our study also suggests two other points that are relevant to document design:

1. It is very important to seek expert help when revising a document. Before we consulted the lawyers and researched the issue of informed consent, we hadn't really understood the purpose of consent forms.

2. It may be difficult to produce a document that will be acceptable to all of the people who use it. In the case of consent forms, until all patients are willing to be fully informed about their condition and treatment, and until all doctors are willing to inform them, it will be difficult to produce ideal documents.

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